

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

28.10.2005

Applicant's or agent's file reference
F18239 JAL

REPLY DUE

within 1 month(s)
from the above date of mailing

International application No.
PCT/IB2004/002863

International filing date (day/month/year)
03.09.2004

Priority date (day/month/year)
09.09.2003

International Patent Classification (IPC) or both national classification and IPC
A61N2/00

Applicant

MAUDARBOCUS, Siddick Mohamed Ahad et al.

1. ☒ The written opinion established by the International Searching Authority:
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority
2. This second report contains indications relating to the following items:
☒ Box No. I Basis of the opinion
☐ Box No. II Priority
☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐ Box No. IV Lack of unity of invention
☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒ Box No. VI Certain documents cited
☐ Box No. VII Certain defects in the international application
☒ Box No. VIII Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the International preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 09.01.2006

Name and mailing address of the international preliminary examining authority:



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**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**International application No.
PCT/B2004/002863**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this opinion is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-27 received on 11.07.2005 with letter of 07.07.2005

Drawings, Sheets

1/10-10/10 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
 4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**

 International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 22-27

because:

- ☒ the said international application, or the said claims Nos. 22-27 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search opinion has been established for the said claims Nos. 22-27
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See supplemental sheet for further details

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**International application No.
PCT/IB2004/002863

**Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	2, 4, 6-21
	No: Claims	1, 3, 5
Inventive step (IS)	Yes: Claims	
	No: Claims	2, 4, 6-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations:**see separate sheet**

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)**see separate sheet**

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY
(SEPARATE SHEET)**

International application No.

PCT/IB2004/002863

Re Item III.

The method of treating a subject in need of enhanced sexual function as defined in claims 22-27 is regarded to be a method for therapeutic treatment of the human or animal body. Therefore, said claims have not been searched. Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1(iv) PCT, no international preliminary examination is required to be carried out on these claims.

Re Item V.

- 1 The documents FR 2 554 355 (D4) and US2004/152948 (D5) were not cited in the international search report. Copies of the document are appended hereto.

- 2 **INDEPENDENT CLAIM 1**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D4 discloses a device for implementing and maintaining an erection of the penis (p. 1, l. 2-3), said device having a cuff shaped to receive a flaccid penis (p. 1, l. 22), the cuff being of titanium metal (p. 1, l. 20); and at least one energy source in the form of at least one magnet (p. 1, l. 24-26).

It is indicated, that the **synergetic effect** of using both titanium and magnetism is discussed in D4, see for example p. 1, l. 31-34. For this reason, a combination of D1 with D4 or D2 with D4 is highly relevant with respect to an assessment of inventive step of any amended independent claim.

- 3 **DEPENDENT CLAIMS 2, 6-21**

Dependent claims 2 and 6-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

**WRITTEN OPINION OF THE INTERNATIONAL
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4 DEPENDENT CLAIM 4

The subject-matter of claim 4 appears to meet the requirements of the PCT with respect to novelty and inventive step.

No prior art document published before the priority date of the present application suggests the inclusion of a bioceramic bead or any means for emitting infrared rays to the device defined in claim 1. The infrared rays emitted by the bead(s) upon thermal activation by body temperature are said to have a beneficial effect on the stimulated tissue, which cannot be contested.

Re Item VI.

Since the validity of the priority claimed seems to be questionable for at least some aspects of the present application, in particular for the features defined in claim 4, the relevance of document D5 with respect to its subject-matter is pointed out (see par. [0007] and [0009]).

Re Item VIII.

The features in device claims 2 and 17-19 relate to a method of using the device rather than clearly defining the device in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.